REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claim 38 is currently being amended.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claim 38 is now pending in this application.

I. OBJECTION TO CLAIM 38

To further prosecution, Applicants have amended claim 38 to obviate this objection.

For the record, Applicants note that the objection for "informalities" to the limitation "bringing a CD-16-transformed effector cell Jurkat CD16, into a reaction medium with the monoclonal antibody" is improperly formulated, because the Office gave no reasons for the objection. The Office's requirement that we "clarify" the limitation implies an indefiniteness rejection, but no such rejection is stated.

II. REJECTION FOR INDEFINITENESS

Regarding the indefiniteness rejection, the Office questions why the purpose of the claimed selection method is undefined in the claim. Office Action, page 3, final paragraph.

This is an improper basis for asserting indefiniteness, because the purpose or intended use of an invention need not be claimed. Moreover, purpose or intended use is generally not considered limiting and thus necessarily cannot introduce ambiguity about claim scope.

Accordingly, Applicants request that the Office withdraw this ground of rejection.

III. REJECTION FOR NON-ENABLEMENT

The Office rejected claim 38 as non-enabled by the specification. Office Action, page 4, section 13. The Office questions the specific nature of the interaction between antibodies and the CD 16-transformed effector cell Jurkat CD16:

> The instant claim encompasses in its scope any and all monoclonal antibodies including those that have antigen specificities against cell surface molecules on Jurkat cells. However, the claimed method is based on interaction of Fc region of an antibody and CD 16 receptor on Jurkat cells and the method correlates the secretion of IL-2 by Jurkat/CD 16 cells and the CD 16 mediated ADCC function (e.g. see Figure 4 of the instant specification). Therefore, it is not clear antibodies that would have antigen specificities to Jurkat/CD 16 cell surface molecules, such as anti-CD16 antibody or anti-CD3 antibody, would be applicable to the claimed methods since those antibodies interact with Jurkat/CD 16 via antigen binding region of the antibodies.

Applicants traverse, for the following reasons. First, as noted below, Applicants have attached test data showing that the claimed invention relates to any antibodies, regardless of specificity.

Second, no undue experimentation is needed to carry out the steps of claim 38. The specification clearly sets forth how to carry out each of the three steps a)-c), and a person of ordinary skill in the art would have no difficulty in carrying out each of these steps. The Office has not explained how it would require undue experimentation to carry out the first step a) (as amended) of

> a) bringing into contact a CD16-transformed effector cell Jurkat CD16 in a reaction medium in the presence of the monoclonal antibody and the antigen for said antibody

The Office has not explained how it would require undue experimentation to carry out the second step b) of:

> b) measuring the amount of IL-2 cytokine released

The Office has not explained how it would require undue experimentation to carry out the third step c) of:

> c) selecting an antibody for which the level of said IL-2 release is increased by more than 100% compared with a negative control

Each of the steps a)-c) would be simple and straightforward for a person of ordinary skill in the art to carry out upon review of the present specification.

The Office emphasizes the "wherein" clause: "wherein the measurement of the amount of IL-2 is linearly correlated to the CD16-specific ADCC activity". Specifically, the Office stated:

> For example, the instant specification clearly shows that anti-CD16 antibody 3G8 inhibits ADCC function (e.g. see Figure 3 and page 11 of the instant specification). It is not clear how monoclonal anti-CD16 antibody can be selected by the claimed method by correlating IL-2 production and ADCC. In addition, Vivier et al. (International Immunity 1992,4; 1 1 : 13 13- 1323, reference on PTO-892 mailed on November 30,2005) teach that Jurkat cells over-expressing CD16 loss CD3:TCR on the cell surface, resulting in the lost of IL-2 production upon stimulation of anti-CD3 antibody (e.g. see right column on page 1321). Thus, the claimed method would not be able to select anti-CD3 antibody based on correlating IL-2 release and ADCC function.

The limitation "wherein the measurement of the amount of IL-2 is linearly correlated to the CD16-specific ADCC activity" confirms the relevance of the measurement and selection steps. This limitation refers to the invention as a whole, and not merely to step c) as the Office appears to suggest. As such, the limitation does not add any burden to the performance of step c) of the claimed invention.

Accordingly, Applicants request that the Office withdraw this ground of rejection.

IV. REJECTION FOR LACK OF WRITTEN DESCRIPTION (NEW MATTER)

The Office rejected claim 38 for new matter in the "linearly correlated" limitation. Office Action, page 6, section 16).

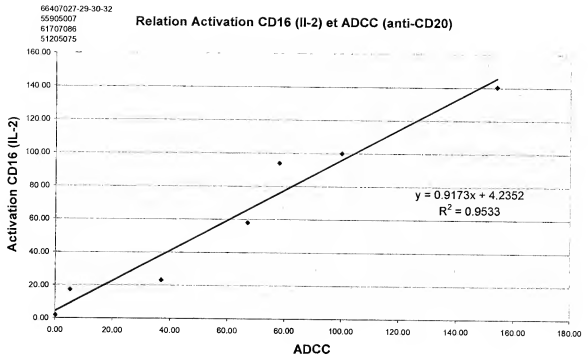
Applicants traverse, because the specification as filed clearly conveys to a person of ordinary skill in the art that, in the context of the invention, "the measurement of the amount of IL-2 is linearly correlated to the CD16-specific ADCC activity".

"An objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.'" M.P.E.P. § 2163.02 (quoting *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989)). "The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement." *Id.*

A person of ordinary skill in the art would recognize from the specification as filed that Applicants considered the invention to relate to any antibodies where such linear correlation exists. This suffices to satisfy the written description requirement in the context of new matter.

V. TEST DATA CONFIRMING LINEAR CORRELATION

Applicants provide the following results of tests with anti-CD20 antibodies indicating a linear correlation between the amount of IL-2 and CD 16-specific ADCC activity. These data support the arguments presented above, that the claimed invention relates to any antibodies, regardless of specificity.



IL-2 61707086

	R603 06-331 LFB	632 06 036 Xencor EMAB	632 06 037 genetech EMAB	632 07 051 Xencor	632 07 052 Genentech
Emax	11722	11943	11064	11525	11049
EC50	0,4061	1,79	0,4078	0,2845	0,6601

Emax/EC50 28864.81162 6672.06704 27130.9465 40509.6661 16738.373

ADC 66407027-29-30-32

	Xencor EMAB	Xencor	Genentech EMAB	Genentech	R603 LFB	Rituxan
Emax/EC50 Rel	0,37	1,54	0,78	0,67	1,00	0,10

	activation CD16	activation CD	ADCC	
R603	28864.81162	100.00	100.00	
63206036	6672.067039	23.11	37.00	61707027_29-30-32 et IL2 61707086
63206037	27130.94654	93.99	78.00	
63207051	40509.66608	140.34	154.00	ADC 55905007 IL-2 51205075
63207052	16738.37297	57.99	67.00	
CD20 CHO ALIQUOT 05/002		17.31	5.20	
RTX ALIQUOT 05/001		1.74	0.15	

CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 6-FEB-2009

By 

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